



ASX AND MEDIA RELEASE

Initiation of US skin cancer trial, update on US AK trial

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Start of new US BCC phase II clinical trial

Peplin Limited (ASX:PEP) today announced the initiation of a second phase II clinical trial (PEP005-009) to further evaluate the safety and efficacy of PEP005 Topical, its proprietary product candidate for the treatment of superficial forms of basal cell carcinoma (BCC), the most common form of skin cancer.

The clinical trial, which will be conducted at multiple sites in the US, will assess several dose levels of PEP005, using a dose escalation format and has the goal of optimising the dose and dosing schedule of PEP005 Topical for this disease.

The trial will define the maximum tolerated dose (MTD) of PEP005 Topical gel when applied to a superficial BCC (sBCC) either with one application (Treatment Arm 1) or two applications of drug, one week apart (Treatment Arm 2). To evaluate the clearance rate of sBCC tumours at the respective maximum tolerated doses the trial will then treat an additional 25 patients in each arm.

Peplin Chief Executive Officer Michael Aldridge said "In earlier clinical trials we have seen clear evidence of the ability of PEP005 Topical to eradicate superficial BCC tumours with just two applications and some evidence that a single application may be effective. We have also observed higher clearance rates with higher concentrations.

"Accordingly, we believe the drug may be even more effective at higher doses. The goal of this trial is to establish PEP005 Topical's clearance rates at the optimal dose. The study will also evaluate the optimal dosing schedule, comparing one and two day applications."

Update on US AK phase II clinical trial

In addition, Peplin provides an update to its presently ongoing US phase IIb actinic (solar) keratosis (AK) clinical trial (PEP005-006). AK is a common skin condition which can develop into skin cancer. This trial has successfully completed enrolment of 103 of the target 200 target subjects. Based on present enrolment rates, Peplin expects to announce results of this trial in the middle of 2007.

Details of the PEP005-009 clinical trial are set out below

The clinical trial (PEP005-009) is an open label, multi-centre, dose escalation cohort study to determine the maximum tolerated dose (MTD) and safety of PEP005 Topical gel when administered either as a single application or two applications to a single superficial basal cell carcinoma on the trunk.

Treatment with PEP005 Topical gel at escalating dosages will be in one of two treatment arms. Arm 1 is a single application and Arm 2 is two applications of drug with treatment on day 1 and day 8. Patients will be treated and evaluated by a healthcare professional in an outpatient setting.

The study is being conducted under Peplin's open IND with FDA. The primary study objective is to determine the MTD of PEP005 Topical gel when administered either as a single or as two applications to a selected sBCC lesion. Secondary objectives comprise both histological and clinical evaluation of tumour clearance.

Approximately 25 patients in each arm of the study will be treated at the MTD. The histological sBCC lesion clearance rate will be determined together with the 95% confidence interval around the clearance rate.

Peplin will compare tumour clearance rates in the 1-day versus 2-day treatment arms at their respective MTD's and will evaluate any difference in tumour clearance rates together with any differences in the degree of local skin responses. Based on this evaluation and subject to regulatory approval Peplin intends to select an optimal dose to be evaluated in a subsequent phase III clinical trial. The study will be run at approximately six clinical centres in the US.

Details of the PEP005-006 clinical trial are set out below

The clinical trial (PEP005-006) is a multi-centre, randomised, double-blind, double-dummy, vehicle-controlled study to determine the safety and efficacy of PEP005 Topical gel in patients with actinic keratosis lesions.

Treatment with PEP005 Topical gel at 0.025%, 0.05% or vehicle gel is on either two or three consecutive days. The first treatment is by a trained healthcare professional, subsequent treatments are by the patient at home. Drug will be applied to a 25 cm² contiguous area containing 4 to 8 typical AK lesions on the arm, shoulder, chest, back or scalp.

The study is being conducted under Peplin's open IND with FDA. The trial objectives are to:

1. evaluate the safety and tolerability of PEP005 Topical gel; and
2. to evaluate the efficacy of PEP005 Topical gel.

The three measures of efficacy comprise:

- *Complete AK lesion clearance rate* defined as the proportion of patients at the day 57 post treatment visit with no clinically visible AK lesions in the treatment area
- *Baseline AK lesion clearance rate* defined as the proportion of patients at the day 57 post treatment visit with 100% reduction in the number of AK lesions identified at baseline in the treatment area
- *Partial clearance rate* defined as the proportion of patients at the day 57 post treatment visit with a 75% or greater reduction in the number of AK lesions identified at baseline in the treatment area

The study has initiated 22 clinical centres and will enrol approximately 200 patients in total.

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ABOUT PEPLIN

Peplin is focused on the development and commercialisation of medical dermatology products and in particular a novel topical product to treat skin cancer and pre-cancerous lesions. Peplin's lead compound is PEP005, the first in a new class of investigational agents. Peplin's lead product has shown significant promise in phase II clinical trials for the treatment of actinic (solar) keratosis (AK), a very common pre-cancerous lesion and basal cell carcinoma (BCC), the most common form of skin cancer. Peplin believes the unique benefits of its lead product may include a very short course of therapy and a transient and favourable side effect profile. Peplin's product development activities are supported by the Australian Federal Government under its Pharmaceuticals Partnerships Program.

Peplin's earlier stage pipeline is targeted at leukemia (a blood borne cancer) using its lead compound PEP005 in an intravenous formulation (PEP005 IV) and bladder cancer using an intracavitary or intravesical formulation (PEP005 IC). PEP005 has demonstrated selective and potent anti-leukemia activity in pre-clinical disease models. PEP005 induces apoptosis in leukemia cells via the activation of PKC delta. Peplin holds global proprietary rights for PEP005 and related molecules.

ABOUT BASAL CELL CARCINOMA

Basal cell carcinoma is a cancer which develops from cells in the basal layer of the skin. It is the most common form of skin cancer accounting for ~80% of all skin cancers. Other forms of skin cancer comprise squamous cell carcinoma (~16% of cases) and melanoma (~4% of cases). BCCs typically develop on sun exposed parts of the body and are more prevalent in older Caucasians with a history of sun exposure.

In terms of incidence BCCs are the most common type of cancer found in humans. Based on a 2005 study by The Lewin Group, Inc. for The Society for Investigative Dermatology and The American Academy of Dermatology Association, there are more than one million cases of basal cell carcinoma each year in the US.

The worldwide prevalence of skin cancer is highest in Australia where it accounts for 80% of all new cancer cases diagnosed here each year. According to the Cancer Council of Australia 256,000 Australians were treated for BCC in 2002. Together, basal cell and squamous cell carcinoma are the most costly cancers in Australia, accounting for \$232 million in treatment costs per year.

ABOUT ACTINIC KERATOSIS

AK is a common skin condition characterised by rough, red, scaly patches, crusts or sores on the top layer of skin. If left untreated AKs can progress to squamous cell carcinoma, an invasive skin cancer that can be fatal. AKs usually develop on the face, lips, ears, scalp, neck, forearms and back of hands - areas that are most commonly exposed to the sun.

AKs are the most common pre-cancerous skin lesions worldwide affecting 50% of Caucasians over the age of 40 years with the average patient having 6-8 lesions. The treatment of AKs is the most common dermatologic procedure performed in the out-patient setting. Based on a 2005 study by The Lewin Group, Inc. for The Society for Investigative Dermatology and The American Academy of Dermatology Association, in the US there were 8.2 million treatments of AK in 2004. According to this study 58 million Americans have AK. The worldwide prevalence of AK is highest in Australia.

Current treatment alternatives comprise surgical techniques (primarily cryotherapy) and topical medications (e.g. 5-fluorouracil, imiquimod and diclofenac). Current treatment approaches can cause scarring and hypopigmentation at the treatment site, can be inconvenient or may require long treatment duration for effect.